

### **REMARKS**

Claims 1-13 and 23-25 are cancelled without prejudice, as drawn to nonelected inventions. Applicants reserve the right to prosecute the subject matter of the cancelled claims in related applications. Claims 14-22 are currently pending.

The Examiner has rejected claims 14-22 under 35 U.S.C. § 103(a) as obvious over Bluestein et al. (U.S. Pat. No. 4,780,423) in view of Lucas (U.S. Pat. No. 6,996,538).

The Applicants respectfully disagree with the Examiner's rejections. Claim 14 recites a computer implemented method for preparing a binding-ready biological sample for a binding assay that comprises the steps, inter alia, of:

choosing a robot method for generating said binding-ready biological sample;

generating work instructions for generating said binding-ready biological sample based on said experiment design and said robot method; and

executing said work instructions on robot stations to generate the binding-ready biological sample.

Neither Bluestein nor Lucas disclose or suggest performing these steps to generate a binding-ready biological sample for a binding assay.

Bluestein discloses the use of controlled pore glass particles in heterogeneous fluorescence assays. Example 1 of Bluestein describes obtaining a radioimmunoassay kit and manually preparing and executing the radioimmunoassay, while separately manually preparing and executing a heterogeneous fluorescence assay in order to compare sensitivity of the two assays. Example 3 of Bluestein describes the use of an automated fluorescence immunoassay system (the Screen Machine of Pandex Laboratories, Inc. ("Pandex")) to automatically perform particle concentration fluorescence immunoassays. While the operation of the Pandex Screen Machine for performing the fluorescence immunoassay is automated, there is no teaching that the preparation of the binding-ready biological samples that are supplied to the Pandex Screen Machine is automated.

As described by the developers of the Pandex Screen Machine in Chris MacCrindle et al., *Particle Concentration Fluorescence Immunoassay: A New Immunoassay Technique for Quantification of Human Immunoglobulins in Serum*, CLINICAL CHEMISTRY, Vol. 31, 1487, 1488 (1985) (“MacCrindle;” made of record in the Supplemental Information Disclosure Statement submitted herewith), a binding-ready biological sample is prepared in advance and provided to the Screen Machine. Specifically, the developers of the Screen Machine state:

The *samples* are diluted with the Digiflex™ Pipetting Station (Micromedic Systems, Inc., Horsham, PA 19044) and pipetted into the Epicon™ assay plate (Pandex Laboratories). *Once the reagents and Eipcon [sic] plates are loaded and the basic instrument parameters are selected, all further operations are completely automatic: e.g., positioning the assay plate, pipetting reagents and wash solutions, and concentrating the solid phase.*

MacCrindle at p. 1488, col. 1, 2d¶ (emphasis added). Thus, while the Screen Machine is programmed to automatically perform a fluorescence immunoassay on a pre-prepared sample, the Screen Machine is not enabled to prepare a binding-ready biological sample. Further, the preparation of a binding-ready biological sample, implemented through the choosing, generating, and executing steps of the claims, is not disclosed or suggested by Bluestein’s use of a Pandex Screen Machine, which use is consistent with the description provided by the Screen Machine creators. In contrast to the method recited by claim 14, Bluestein and the Screen Machine creators disclose the automated performance of particle concentration fluorescence immunoassays, but do not disclose the automated preparation of samples. Moreover, the Examiner’s assertion that use of the Screen Machine suggests the preparation of binding-ready biological samples on a robot station as specified in the claims could only be made through the impermissible use of hindsight using the present disclosure as a template because the Screen Machine was specifically designed to be used with pre-prepared samples, and as such, cannot be said to disclose or suggest the choosing, generating, and executing steps of the claims, which relate to sample preparation on a robot station.

Because Bluestein does not disclose or suggest a method for using a robot method to automatically generate a binding-ready biological sample, claim 14 and its dependent claims 15-22 are not made obvious by Bluestein under 35 U.S.C. § 103(a).

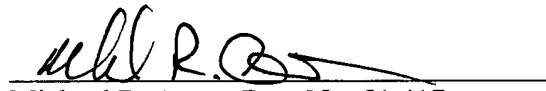
Additionally, Lucas does not make up this deficiency in Bluestein. Lucas is related to an inventory control method and provides no disclosure or suggestion regarding the preparation of binding-ready biological samples. Therefore, because Bluestein combined with Lucas fails to disclose or suggest a method for using a robot station to generate a binding-ready biological sample by the steps of choosing, generating, and executing as specified in the claims, claim 14 and its dependent claims are not made obvious by these references under 35 U.S.C. § 103(a).

Withdrawal of the rejection is thus requested.

### **CONCLUSION**

Entry of the above amendments and consideration of the foregoing remarks are requested. For the reasons discussed above, the Applicants respectfully submit that the application is in condition for allowance, and allowance is requested. The Examiner is invited to call the undersigned to discuss any remaining issues.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Michael R. Asam", is written over a horizontal line.

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